

Remarks

The Applicants have amended the Specification to place it into better form under US Rules of Practice. Entry of those changes into the official file is respectfully requested.

Claim 1 has been amended to further clarify the structure of the claimed device so that it is now referred to as a “stent,” as opposed to a prosthesis. Similar changes have been made to Claims 4, 5, 6, 8, 9 and 15 in accordance with the changes to Claim 1.

Claim 1 has further been amended to recite that the releasable therapeutic agent is coated directly on a surface of the stent which is free from a biocompatible coating. Support may be found in the paragraph spanning pages 41-42 of the original Specification (paragraph [0031] of the published application).

Claims 2, 3, 7 and 14 have been cancelled.

Claim 15 has been amended to include some of the subject matter of cancelled Claim 3.

Entry of the above amendments and cancellations and entry into the official file is respectfully requested inasmuch as they advance the application toward allowance or at least put it into better form for appeal.

Claims 1-5, 7 and 15 stand rejected under 35 USC §102 as being anticipated by Kaplan. The Applicants respectfully submit that the rejection is now moot with respect to cancelled Claims 2, 3, and 7. The Applicants respectfully submit that Kaplan fails to explicitly or implicitly disclose the subject matter of remaining Claims 1, 4 and 5. Details are set forth below.

As noted above, Claim 1 has been amended to clarify the claim structure so that it is now recited as a stent comprising at least one releasable therapeutic unit coated directly on the surface of the stent which is free from a biocompatible coating. The Applicants respectfully submit that

Kaplan fails to disclose such a structure. In that regard, Kaplan is directed primarily to infusion catheters through which an antioxidant drug may be administered for treatment purposes. However, as helpfully noted in the rejection, page 9 of Kaplan refers to stents. However, there is no implicit or explicit disclosure that such stents should comprise at least one releasable therapeutic agent coated directly on a surface of the stent which is free from a biocompatible coating. The Applicants therefore respectfully submit that Kaplan is inapplicable under §102.

Claim 6 stands rejected under 35 USC §103 over the combination of Shanley with Kaplan. The Applicants respectfully submit, however, that both Shanley and Kaplan fail to disclose, teach or suggest the Applicants' claimed stent comprising at least one releasable therapeutic agent coated directly on a surface of the stent which is free from a biocompatible coating and which comprises the generally thin walled structure containing a plurality of struts as specifically recited in Claim 6.

Moreover, the Applicants respectfully submit that, given the common practice of employing biocompatible polymers on various structures that are insertable and/or implantable, those biocompatible polymers which sometimes provoke inflammatory responses as noted in the Applicants' Specification would lead one skilled in the art to have a reasonable expectation that removing such a biocompatible polymer coating would likely provoke a full inflammatory response that the commonly used biocompatible polymers coatings are intended to reduce.

The Applicants nonetheless unexpectedly discovered that removing the coating and applying the melatonin or its derivatives directly to the surface of the stent which is free from a biocompatible coating does not induce inflammation surrounding the struts of the stent upon histological examination. The Applicants respectfully submit that this is unpredictable and one skilled in the art would find such a phenomenon to be surprising indeed. Accordingly, the

Applicants respectfully submit that Claim 6 is anything but obvious over Shanley combined with Kaplan.

Claims 8, 9 and 14 stand rejected under 35 USC §103 over Kaplan. The Applicants respectfully submit that the rejection is now moot with respect to cancelled Claim 14. The Applicants nonetheless respectfully submit that Kaplan fails to provide adequate disclosure, teachings or suggestions as noted above with respect to the combination of Shanley with Kaplan that would render Claims 8 and 9 obvious. Withdrawal of the rejection of Claims 8 and 9 based on Kaplan alone is respectfully requested.

In light of the foregoing, the Applicants respectfully submit that the entire Application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,



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